Complete Summary

GUIDELINE TITLE

Cetuximab for the treatment of recurrent and/or metastatic squamous cell cancer of the head and neck.

BIBLIOGRAPHIC SOURCE(S)

National Institute for Health and Clinical Excellence (NICE). Cetuximab for the treatment of recurrent and/or metastatic squamous cell cancer of the head and neck. London (UK): National Institute for Health and Clinical Excellence (NICE); 2009 Jun. 27 p. (Technology appraisal guidance; no. 172).

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Recurrent and/or metastatic squamous cell cancer of the head and neck (SCCHN)

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Treatment

CLINICAL SPECIALTY

Internal Medicine
Oncology
Otolaryngology

INTENDED USERS

Advanced Practice Nurses
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To evaluate the clinical effectiveness and cost effectiveness of cetuximab for the treatment of recurrent and/or metastatic squamous cell cancer of the head and neck

TARGET POPULATION

Patients with recurrent and/or metastatic squamous cell cancer of the head and neck

INTERVENTIONS AND PRACTICES CONSIDERED

The use of cetuximab for the treatment of recurrent and/or metastatic squamous cell cancer of the head and neck was considered but not recommended.

MAJOR OUTCOMES CONSIDERED

- Clinical effectiveness
    - Overall survival time
    - Progression free survival
    - Tumor response
    - Disease control
    - Time to treatment failure
    - Duration of the response
    - Quality of life
    - Adverse events of treatment
- Cost-effectiveness

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent

academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an Evidence Review Group (ERG) report. The ERG report for this technology appraisal was prepared by Liverpool Reviews and Implementation Group, University of Liverpool (see the "Availability of Companion Documents" field).

Clinical Effectiveness

Description of Manufacturer's Search Strategy and Comment on the Appropriateness of the Chosen Search Strategy

The stated aim of the literature search described in the manufacturer's submission (MS) was to identify studies describing the use of cetuximab in combination with platinum-based chemotherapeutic regimens in the first-line treatment of recurrent and/or metastatic squamous cell cancer of the head and neck (SCCHN). The ERG re-emphasises that the limitation to first-line use was applied by the manufacturer and was not included in the NICE scope.

The search strategy was comprehensive and included the most appropriate databases: MEDLINE (1950 to August week 3 2008), EMBASE (1980 to week 5 2008), DataStar Current Contents (1995 to 3/9/2008), the Cochrane library (3/9/2008) and the American Society of Clinical Oncology (ASCO) abstracts from annual meetings. The manufacturer did not search Institute for Scientific Information (ISI) Web of Knowledge which includes the Science Citation Index and conference proceedings.

The MS presented the search strategy and resulting articles in a self-contained embedded document. The flowchart relating to DataStar Current Contents shows a search total of 89, however the actual numbers quoted total 92. In addition, the file containing the search results contained only 63 references.

With reference to the ASCO search, the ERG found a conference presentation made by the principal investigator of the EXTREME trial at the 2007 ASCO conference which did not appear in the manufacturer's search results for ASCO.

Statement of the Inclusion/Exclusion Criteria Used in the Study Selection and Comment on Whether They Were Appropriate

Inclusion Criteria

- Randomised controlled trials (RCTs)
- Studies of the use of cetuximab in the first-line treatment of recurrent and/or metastatic head and neck cancer
- Human only studies
- Studies in English

Exclusion Criteria

- Studies which involved patients who had received previous treatment in the metastatic and/or recurrent head and neck cancer setting
- Papers published in a language other than English

- Letters and editorials
- Review articles and conference summaries

The inclusion/exclusion criteria described in the MS are appropriate to the manufacturer's stated objectives, focused on cetuximab as a first-line treatment.

The MS lists three relevant RCTs (two phase III trials and one phase II trial). The EXTREME trial was included in the review. The remaining two trials were excluded from the literature review by the manufacturer.

The ERG did not find any other relevant studies for inclusion in the review.

Economic Evaluation

The manufacturer conducted a review of the literature to retrieve cost-effectiveness studies relevant to the decision problem of cetuximab for the first-line treatment of patients with recurrent and/or metastatic SCCHN.

Identification and Description of Studies

The MS included full details of the electronic search strategy used in the review by the manufacturer. The databases searched were described with dates and included MEDLINE, EMBASE, National Health Service Economic Evaluation Database (NHS EED) and Health Economic Evaluation Database (HEED). All searches were conducted over relevant time periods.

Stated clinical related inclusion criteria were: metastatic head and neck cancer, recurrent head and neck cancer, metastatic/recurrent SCCHN and cetuximab. These terms were combined with the following economic related terms: cost effectiveness analysis, cost benefit analysis, quality-adjusted life year (QALY), cost effectiveness and quality of life (QoL).

Using these criteria no relevant studies were identified for inclusion in the review. Neither the MEDLINE nor the EMBASE searches identified any economic analyses in the treatment of recurrent and/or metastatic head and neck cancer. Several studies were identified by the NHS EED (n=3) and the HEED (n=15) searches. The manufacturer excluded these studies from the review.

Summary and Conclusions

The manufacturer's review of the cost-effectiveness evidence available for cetuximab as a first-line treatment of recurrent and/or metastatic SCCHN is adequate. The ERG is confident that the manufacturer did not miss any relevant articles in its searches of the published literature. No details of any searches undertaken to identify unpublished data held by the manufacturer were presented in the MS; therefore, the ERG cannot comment further on this issue.

NUMBER OF SOURCE DOCUMENTS

Clinical Effectiveness

One randomized controlled trial (RCT) was included in the review.

Cost-Effectiveness

A manufacturer's model was submitted.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an Evidence Review Group (ERG) report. The ERG report for this technology appraisal was prepared by Liverpool Reviews and Implementation Group, University of Liverpool (see the "Availability of Companion Documents" field).

Clinical Effectiveness

Description and Critique of Manufacturer's Approach to Validity Assessment

The manufacturer commented on relevant aspects of the quality of the EXTREME trial, namely: allocation concealment; randomisation technique; powering; follow-up; blinding; relevance to the UK; baseline comparability of groups; statistical analyses; type of analysis. The manufacturer described the EXTREME trial as an open label randomised controlled trial (RCT). Randomisation was stratified according to the most important prognostic factors: previous chemotherapy treatment (CTX) and Karnofsky performance score (KPS). A central stratified, permuted block randomisation procedure was used to balance prognostic factors and to minimise the predictability of treatment allocation.

The manufacturer's approach to validity was reasonable in most respects, although the open label nature of the EXTREME trial warrants further discussion. It is well documented that open studies are more likely to favour experimental interventions over controls and studies that are not double-blinded can exaggerate effect estimates by 17%.

Patient awareness of treatment allocation has also been shown to affect treatment outcomes, although the use of a placebo control in this setting would be considered unethical.

Description and Critique of Manufacturers Outcome Selection

The outcome measures presented in the manufacturer submission (MS) are shown in Table 4.5 of the ERG report (see the "Availability of Companion Documents" field). These are standard outcomes for a trial of this type and match those specified in the scope.

Description and Critique of the Statistical Approach Used

In terms of powering, the EXTREME trial assumed a median survival of seven months and an approximate increase of 36% in median survival with the addition of cetuximab to the platinum-based CTX. It was calculated that an event-driven analysis after 340 deaths would provide the study with a power of 80% to detect a difference at a two-sided, 5% significance level. Random assignment to study groups of a total of 420 patients within 20 months would lead to estimated total study duration of 34 months (with the assumption that 5% of patients would be lost to follow-up).

Full details of the Cox regression modelling approach undertaken are described in the published paper*. In contrast to the MS, the published paper fully describes the statistical approaches and techniques used by the manufacturer and the ERG considers the methods to be appropriate.

*Vermorken Jan B, et al. Platinum-based chemotherapy plus cetuximab in head and neck cancer. NEJM, 2008. 359(11): p. 1116-27.

Economic Evaluation

Model Validation

The manufacturer states that the model structure and assumptions were validated by a UK expert panel and provides the supporting meeting notes from the Merck Serono Health Economic Advisory Board Meeting.

Sensitivity Analyses

Univariate sensitivity analysis (SA) and probabilistic sensitivity analysis (PSA) were conducted by the manufacturer for selected model parameters. The results of the main SA are presented in Table 5.12 of the ERG report (see the "Availability of Companion Documents" field). Varying the cost of day case infusion and changing the utility values in the stable/response health state of the cetuximab arm have the greatest impact on the incremental cost-effectiveness ratio (ICER).

The manufacturer conducted further SA in order to assess the impact of higher or lower adverse event (AE) costs. The AE profile report rates are similar across both treatment arms and changing the cost of an AE does not affect the size of the ICER.

For the PSA, scatter plots (incremental cost versus life years, incremental cost versus quality-adjusted life years [QALYs]) and a cost-effectiveness acceptability curve (CEAC) were calculated as shown in Figure 5-2 and Figure 5-3 of the ERG report (see the "Availability of Companion Documents" field).

Critique of Manufacturer's Economic Model

The economic model submitted by the manufacturer is implemented to a generally high standard and is clearly presented. The layouts of the various elements of the model are generally logical, and the formulae employed are straightforward.

Refer to Section 5 of the ERG report (see the "Availability of Companion Documents" field) for more information.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Considerations

Technology appraisal recommendations are based on a review of clinical and economic evidence.

Technology Appraisal Process

The National Institute for Health and Clinical Excellence (NICE) invites 'consultee' and 'commentator' organisations to take part in the appraisal process. Consultee organisations include national groups representing patients and carers, the bodies representing health professionals, and the manufacturers of the technology under review. Consultees are invited to submit evidence during the appraisal and to comment on the appraisal documents.

Commentator organisations include manufacturers of the products with which the technology is being compared, the National Health Service (NHS) Quality Improvement Scotland and research groups working in the area. They can comment on the evidence and other documents but are not asked to submit evidence themselves.

NICE then commissions an independent academic centre to review published evidence on the technology and prepare an 'assessment report'. Consultees and commentators are invited to comment on the report. The assessment report and the comments on it are then drawn together in a document called the evaluation report.

An independent Appraisal Committee then considers the evaluation report. It holds a meeting where it hears direct, spoken evidence from nominated clinical experts, patients and carers. The Committee uses all the evidence to make its first recommendations, in a document called the 'appraisal consultation document'

(ACD). NICE sends all the consultees and commentators a copy of this document and posts it on the NICE website. Further comments are invited from everyone taking part.

When the Committee meets again it considers any comments submitted on the ACD; then, it prepares its final recommendations in a document called the 'final appraisal determination' (FAD). This is submitted to NICE for approval.

Consultees have a chance to appeal against the final recommendations in the FAD. If there are no appeals, the final recommendations become the basis of the guidance that NICE issues.

Who is on the Appraisal Committee?

NICE technology appraisal recommendations are prepared by an independent committee. This includes health professionals working in the NHS and people who are familiar with the issues affecting patients and carers. Although the Appraisal Committee seeks the views of organisations representing health professionals, patients, carers, manufacturers and government, its advice is independent of any vested interests.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

The manufacturer developed a two-arm state-transition Markov model to evaluate the cost effectiveness of cetuximab plus chemotherapy compared with chemotherapy alone. The clinical data used in the economic evaluation were generated from the EXTREME study. Although the economic evaluation was trial-based, there was a modelling component that allowed extrapolation of health effects beyond the period of the study (24 months).

The categories of costs used in the economic model included chemotherapy drugs (cetuximab, cisplatin, carboplatin and fluorouracil), drug administration, treatment of adverse events, palliative-intent chemotherapy drugs, palliative-intent surgery and palliative-intent radiology.

The results of the base-case scenario for cetuximab plus chemotherapy compared with chemotherapy alone gave an incremental cost-effectiveness ratio (ICER) of 121,367 pounds sterling per quality-adjusted life year (QALY) gained.

In addition to the base-case scenario, the manufacturer also presented ICERs for subgroups by tumour location and for metastatic disease and recurrent disease subgroups. The ICERs presented were as follows:

- Oropharynx and oral cavity, ICER of 105,069 pounds sterling per QALY gained
- Oropharynx and oral cavity with Karnofsky performance status (KPS) of 90 or more, ICER of 97,702 pounds sterling per QALY gained
- Oropharynx, ICER of 250,597 pounds sterling per QALY gained

- Oropharynx with KPS of 90 or more, ICER of 309,735 pounds sterling per QALY gained
- Oral cavity, ICER of 63,927 pounds sterling per QALY gained
- Oral cavity with KPS of 90 or more, ICER of 54,791 pounds sterling per QALY gained
- Metastatic disease including recurrent disease, ICER of 562,849 pounds sterling per QALY gained
- Metastatic disease excluding recurrent disease, dominated
- Recurrent disease, ICER of 87,099 pounds sterling per QALY gained

The Evidence Review Group (ERG) identified a number of potential issues related to the manufacturer's economic submission, which were considered to compromise the validity of the model results.

The ERG considered that it was likely that at least some of the subgroups were too small to yield reliable projection models, casting doubt on the credibility of the cost-effectiveness results for those subgroups.

The ERG carried out exploratory analysis using alternative assumptions and parameters in the economic model.

The combined effects of the ERG's exploratory analysis on the original base case resulted in ICERs of 166,307 pounds sterling and 208,266 pounds sterling per QALY gained when based on a lifetime and a 24-month time horizon, respectively. The ERG also carried out exploratory analysis to determine the effect of its model amendments on all the patient subgroups. In all cases, the results of the analyses showed that cetuximab plus chemotherapy was less cost-effective with the ERG model and parameter corrections and amendments than when modelled by the manufacturer.

In response to the consultation on the preliminary guidance, the manufacturer submitted cost-effectiveness analyses for additional subgroups based on age (younger than 65 years) and KPS (KPS of 90 or more and KPS of 80 or more). The cost-effectiveness estimates presented for these subgroups were obtained using the manufacturer's original economic model. The subgroup analysis for patients younger than 65 years with a KPS of 90 or more gave an ICER of 92,804 pounds sterling per QALY gained and predicted life years gained of 0.314 (equating to an overall survival benefit from cetuximab plus chemotherapy of 3.77 months). The subgroup analysis for patients younger than 65 years with a KPS of 80 or more gave an ICER of 124,400 pounds sterling per QALY gained and predicted life years gained of 0.188 (equating to an overall survival benefit from cetuximab plus chemotherapy of 2.25 months).

The Committee reviewed the additional cost-effectiveness analyses submitted by the manufacturer for additional subgroups based on age (younger than 65 years) and Karnofsky performance status (KPS) (KPS of 90 or more and KPS of 80 or more).

The Committee was not persuaded that the evidence provided by the manufacturer supported the predicted life years gained for the combined age and KPS subgroup. On this basis, the Committee concluded that the estimates of cost-

effectiveness for the subgroup of patients who were younger than 65 years with a KPS of 90 or more could not be considered reliable.

The Committee concluded that cetuximab, given in combination with platinum-based chemotherapy for the treatment of recurrent and/or metastatic squamous cell cancer of the head and neck (SCCHN), could not be recommended as a cost-effective use of National Health Service (NHS) resources.

Refer to Sections 3 and 4 of the original guideline document for details of the economic analyses provided by the manufacturer, the ERG comments, and the Appraisal Committee considerations.

METHOD OF GUIDELINE VALIDATION

External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Consultee organizations from the following groups were invited to comment on the draft scope, Assessment Report and the Appraisal Consultation Document (ACD) and were provided with the opportunity to appeal against the Final Appraisal Determination.

- Manufacturer/sponsors
- Professional/specialist and patient/carer groups
- Commentator organisations (without the right of appeal)

In addition, individuals selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups were also invited to comment on the ACD.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Cetuximab in combination with platinum-based chemotherapy is not recommended for the treatment of recurrent and/or metastatic squamous cell cancer of the head and neck.

People currently receiving cetuximab in combination with platinum-based chemotherapy for the treatment of recurrent and/or metastatic squamous cell cancer of the head and neck should have the option to continue treatment until they and their clinician consider it appropriate to stop.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The Appraisal Committee considered evidence submitted by the manufacturer of cetuximab and a review of this submission by the Evidence Review Group.

The main evidence of the efficacy of cetuximab in the manufacturer's submission was obtained from one randomized controlled trial. The clinical data used in the economic evaluation were generated from the same trial.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate recommendation for the use of cetuximab for the treatment of recurrent and/or metastatic squamous cell cancer of the head and neck

POTENTIAL HARMS

One common adverse effect of cetuximab treatment is the development of skin reactions, which occur in more than 80% of patients. These mainly present as an acne-like rash or, less frequently, as pruritus, dry skin desquamation, hypertrichosis or nail disorders (for example, paronychia). The majority of skin reactions develop within the first 3 weeks of treatment. The summary of product characteristics (SPC) notes that if a patient experiences a severe skin reaction, cetuximab treatment must be interrupted. Treatment should be resumed only when the reaction resolves, and affects less than 50% of the surface area of the skin. Other common adverse effects of cetuximab treatment include mild or moderate infusion-related reactions such as fever, chills, nausea, vomiting, headache, dizziness or dyspnoea that occur soon after the first cetuximab infusion. Treatment with cetuximab in combination with platinum-based chemotherapy may increase the frequency of severe leukopenia or severe neutropenia, and may lead to a higher rate of infectious complications such as febrile neutropenia, pneumonia and sepsis compared with platinum-based chemotherapy alone.

For full details of side effects and contraindications, see the SPC.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- This guidance represents the view of the National Institute for Health and Clinical Excellence (NICE), which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

- Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The Healthcare Commission assesses the performance of National Health Service (NHS) organisations in meeting core and developmental standards set by the Department of Health in 'Standards for better health' issued in July 2004. The Secretary of State has directed that the NHS provides funding and resources for medicines and treatments that have been recommended by National Institute for Health and Clinical Excellence (NICE) technology appraisals normally within 3 months from the date that NICE publishes the guidance. Core standard C5 states that healthcare organisations should ensure they conform to NICE technology appraisals.

'Healthcare standards for Wales' was issued by the Welsh Assembly Government in May 2005 and provides a framework both for self-assessment by healthcare organisations and for external review and investigation by Healthcare Inspectorate Wales. Standard 12a requires healthcare organisations to ensure that patients and service users are provided with effective treatment and care that conforms to NICE technology appraisal guidance. The Assembly Minister for Health and Social Services issued a Direction in October 2003 that requires local health boards and NHS trusts to make funding available to enable the implementation of NICE technology appraisal guidance, normally within 3 months.

NICE has developed tools to help organisations implement this guidance (listed below). These are available on the NICE website (http://guidance.nice.org.uk/TA172).

- A costing statement explaining the resource impact of this guidance
- Audit support for monitoring local practice

IMPLEMENTATION TOOLS

Audit Criteria/Indicators
Foreign Language Translations
Patient Resources
Quick Reference Guides/Physician Guides
Resources

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

End of Life Care
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

National Institute for Health and Clinical Excellence (NICE). Cetuximab for the treatment of recurrent and/or metastatic squamous cell cancer of the head and neck. London (UK): National Institute for Health and Clinical Excellence (NICE); 2009 Jun. 27 p. (Technology appraisal guidance; no. 172).

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2009 Jun

GUIDELINE DEVELOPER(S)

National Institute for Health and Clinical Excellence (NICE) - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

National Institute for Health and Clinical Excellence (NICE)

GUIDELINE COMMITTEE

Appraisal Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: Professor Keith Abrams, Professor of Medical Statistics, University of Leicester; Dr Ray Armstrong, Consultant Rheumatologist, Southampton General Hospital; Dr Jeff Aronson, Reader in Clinical Pharmacology, University Department of Primary Health Care, University of Oxford; Dr Darren

Ashcroft, Reader in Medicines Usage and Safety, School of Pharmacy and Pharmaceutical Sciences, University of Manchester; Professor David Barnett (*Chair*), Professor of Clinical Pharmacology, University of Leicester; Dr Peter Barry, Consultant in Paediatric Intensive Care, Leicester Royal Infirmary; Professor John Cairns, Public Health and Policy, London School of Hygiene and Tropical Medicine; Dr Mark Chakravarty, External Relations Director – Pharmaceuticals & Personal Health, Oral Care Europe; Professor Jack Dowie, Health Economist, London School of Hygiene and Tropical Medicine; Dr Martin Duerden, Medical Director, Conwy Local Health Board; Ms Lynn Field, Nurse Director, Pan Birmingham Cancer Network; Dr Fergus Gleeson, Consultant Radiologist, Churchill Hospital, Oxford; Ms Sally Gooch, Independent Nursing and Healthcare Consultant; Mrs Eleanor Grey, Lay Member; Mr Terence Lewis, Lay Member, Mental Health Consultant, National Institute for Mental Health in England; Professor Gary McVeigh, Professor of Cardiovascular Medicine, Queens University, Belfast; Dr Ruairidh Milne, Senior Lecturer in Public Health, National Coordinating Centre for Health Technology; Dr Neil Milner, General Practitioner, Tramways Medical Centre, Sheffield; Dr John Pounsford, Consultant Physician, Frenchay Hospital, Bristol; Dr Rosalind Ramsay, Consultant Psychiatrist, Adult Mental Health Services, Maudsley Hospital; Dr Stephen Saltissi, Consultant Cardiologist, Royal Liverpool University Hospital; Dr Lindsay Smith, General Practitioner, East Somerset Research Consortium; Mr Roderick Smith, Finance Director, West Kent Primary Care Trus; Mr Cliff Snelling, Lay Member; Professor Ken Stein, Professor of Public Health, Peninsula Technology Assessment Group (PenTAG), University of Exeter; Professor Andrew Stevens, Professor of Public Health, Department of Public Health and Epidemiology, University of Birmingham; Dr Rod Taylor, Associate Professor in Health Services Research, Peninsula Medical School, Universities of Exeter and Plymouth; Ms Nathalie Verin, Health Economics Manager, Boston Scientific UK and Ireland; Dr Colin Watts, Consultant Neurosurgeon, Addenbrooke's Hospital; Mr Tom Wilson, Director of Contracts and Information Management and Technology, Milton Keynes PCT

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) format from the National Institute for Health and Clinical Excellence (NICE) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Cetuximab for the treatment of recurrent and/or metastatic squamous cell cancer of the head and neck. Quick reference guide. London (UK): National Institute for Health and Clinical Excellence (NICE); 2009 Jun. 2 p. (Technology appraisal 172). Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. ref: N1889. 11 Strand, London, WC2N 5HR.

The following are also available:

- Cetuximab for the treatment of recurrent and/or metastatic squamous cell cancer of the head and neck. Costing statement. London (UK): National Institute for Health and Clinical Excellence (NICE); 2009 Jun. 2 p. (Technology appraisal 172). Available in Portable Document Format (PDF) from the NICE Web site.
- Cetuximab for the treatment of recurrent and/or metastatic squamous cell cancer of the head and neck. Audit support. Implementing NICE guidance. London (UK): National Institute for Health and Clinical Excellence (NICE); 2009. 6 p. (Technology appraisal 172). Available in Portable Document Format (PDF) from the NICE Web site.
- Head and neck cancer (squamous cell carcinoma): cetuximab. Evidence review group report. Liverpool Reviews and Implementation Group; 2009. 82 p. Available in Portable Document Format (PDF) from the NICE Web site.

PATIENT RESOURCES

The following is available:

- Cetuximab for recurrent and/or metastatic squamous cell cancer of the head and neck. Understanding NICE guidance. Information for people who use NHS services. London (UK): National Institute for Health and Clinical Excellence (NICE); 2009 Jun. 4 p. (Technology appraisal 172). Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site. Also available in Welsh from the NICE Web site.

Print copies: Available from the NHS Response Line 0870 1555 455. ref: N1890. 11 Strand, London, WC2N 5HR.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This NGC summary was completed by ECRI Institute on April 9, 2010.

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